IV. Hypoallergenic Formulas

Hydrolyzed formulas are similar to milk based and soy based formulas with changes made to the protein component. They meet the requirements established by the American Academy of Pediatrics, Committee on Nutrition for the minimum level of 29 nutrients and the maximum level of 9 nutrients. The milk protein (whey or casein) is heat treated and broken down enzymatically to create a protein that is easier to digest. These infant formulas were designed for infants who have problems with the digestion of protein or severe allergy problems to protein. In many cases these formulas are provided to infants with feeding problems or enzyme deficiencies, such as cystic fibrosis. **Most of the protein hydrolysate formulas are lactose free due to the use of sucrose, tapioca starch, corn syrup solids or cornstarch**. The fat in these formulas may contain medium-chain triglycerides (MCT), which are also easier to digest and absorb. Due to the changes in the fat component, some of these formulas are also useful for problems with fat malabsorption, short gut syndrome and severe chronic diarrhea.

Elemental (amino acid) formulas are indicated for confirmed diagnoses of: eosinophilic esophagitis, eosinophilic enteropathy, documented anaphylaxis (pending consultation with allergist), or upon consultative recommendation of an allergist or pediatric gastroenterologist.

All hydrolysate and elemental formulas must be prescribed by a licensed health care provider prior to issuance. According to WIC Federal Regulations (7 CFR, Part 246), monthly formula issuance amounts are based on infant age, feeding choice (partially breastfed or fully formula fed) and form of formula (powder, concentrate, ready to feed). Partially breastfed infants needing supplemental formula may receive a maximum of one can of powdered formula in the first 30 days of life, and will have monthly issuance tailored according to individual need throughout the rest of the first year. WIC maximum formula issuance amounts for all age groups, infant feeding choices and forms of formula are included for each item listed.

For WIC participants who are enrolled in the MaineCare program:

- Hydrolysate formulas will be provided by WIC up to the federal maximum issuance per month. Any medically necessary amounts needed over WIC's federal maximum will be provided by MaineCare.
- All elemental formulas will be provided by MaineCare

If the infant is not enrolled in MaineCare:

• The Maine CDC WIC Nutrition Program will provide the formula in amounts not to exceed the federal maximum issuance per month.

Prescriptions for these formulas must include:

- specific formula name
- diagnosis
- · length of time the product is needed
- · amount of formula prescribed per day

Health care providers may use the *Maine CDC WIC Nutrition Program/MaineCare Request/Prior Authorization for Medical Formula/WIC-Eligible Nutritionals* form to obtain approval and prior authorization for MaineCare coverage. This form must be sent to the local WIC office in order for MaineCare to approve coverage of the formula prescribed.

Hypoallergenic	Formulas—Hyd	drolysates						
Product Name	Description	Packaging	Composition	Indications	Maximum	Monthly W	IC Issuance	Amounts
Nutramigen® and Nutramigen® with Enflora TM LGG® (Mead Johnson	Nutritionally complete extensively hydrolyzed protein formula for infants. Lactose Free Sucrose Free	Powder: 12.6 oz. cans, 6 cans/case (use packed level scoops) Can yield = 87 fl. oz. (standard dilution) NDC: 0087-123941	CHO: corn syrup solids, modified corn starch PRO: hydrolyzed casein, Lamino acids FAT: palm olein, soy, coconut, high oleic sunflower,	Formula for infants and children with sensitivity to intact proteins of milk and other foods, infants with galactosemia, or infants with severe or	Non- breastfed infants Powder: 12.6 oz. RTF (32 oz.)	0-3 months 10 cans 26 cans	4-5 months 11 cans 28 cans	8 cans 20 cans
Nutrition) Sucro Galact Conta knowr	Galactose Free Contains no known sources of gluten	Ready to Feed Liquid: 32 oz. cans, 6 cans/case NDC: 0087-049901	Probiotic: Lactobacillus rhamnosus GG (powder only) Vitamins, minerals	multiple food allergies, including allergy to intact proteins in cow's milk and soy formulas.	Partially breastfed infants	416 nursettes 1-3 months	448 nursettes 4-5 months	320 nursettes 6-11 months
	Note: Nutramigen is available in <i>ready</i> to <i>feed</i> only. 2 oz nursettes, 48 nursettes per case to <i>feed</i> only. 2 oz nursettes, 48 nursettes per case nursettes per case to <i>feed</i> only. 300 mOsm/kg H ₂ O (powder) >12 months, dietary calcium of the companient of t	If used as a milk substitute for children >12 months, total dietary calcium should be assessed for	Powder: 12.6 oz. RTF (32 oz.) RTF (2 oz.)	5 cans 12 cans 192 nursettes	6 cans 14 cans 224 nursettes	4 cans 10 cans 160 nursettes		
Similac Expert Care® Alimentum® (Abbott Nutrition)	powder only. Nutritionally complete hypoallergenic infant formula,	Powder: 16 oz. cans, 6 cans/case (use unpacked level scoops) Can yield = 115 fl. oz.	CHO: corn maltodextrin, sucrose (powder); sucrose, modified tapioca starch (RTF) PRO: casein hydrolysate , L-	For infants with colic symptoms due to protein sensitivity, including severe food	Non- breastfed infants Powder:	0-3 months	4-5 months	6-11 months
	containing a predigested protein for babies with cow's milk protein allergies	(standard dilution of 20kcal/oz) NDC: 70074-0576-64 Ready to Feed Liquid:	amino acids FAT : high oleic safflower, MCT, soy, M. alpina and C. cohnii oils, DATEM (powder); safflower, MCT, soy, M.	allergies, sensitivity to intact protein, protein maldigestion or fat malabsorption	16 oz. RTF (2 oz.) Partially	7 cans 26 cans 416 nursettes	8 cans 28 cans 448 nursettes	6 cans 20 cans 320 nursettes
	33% fat from MCT Lactose Free.	32 oz. bottles, 6 cans/case; NDC: 70074-0575-13	alpina and C. cohnii oils (RTF) Vitamins, minerals		breastfed infants Powder: 16 oz.	1-3 months 3 cans	4-5 months 4 cans	6-11 months 3 cans
	Gluten Free RTF is also Corn Free.	2 fl. oz. nursettes, 48/case	20 cal./fl.oz. Osmolality= 320 mOsm/kg H ₂ O (powder) 370 mOsm/kg H ₂ O (RTF)		RTF (32 oz.) RTF (2 oz.)	12 cans 192 nursettes	14 cans 224 nursettes	10 cans 160 nursettes

Hypoallergenic	Formulas—Hy	drolysates						
Product Name	Description	Packaging	Composition	Indications	Maximum	Monthly W	IC Issuance	Amounts
Pregestimil® (Mead Johnson Nutrition™)	Nutritionally complete infant formula with easily digested protein, fat and carbohydrate sources. 55% of fat from MCT. Lactose Free Galactose Free Contains no known sources	Powder: 16 oz. cans, 6 cans/case (use packed level scoops) Can yield = 112 fl. oz. (standard dilution) NDC: 0087-036701 Ready to Feed Liquid: 20 cal/ounce: 2 oz. nursettes, 48 nursettes/case	CHO: corn syrup solids, modified corn starch; dextrose (powder only) PRO: hydrolyzed casein, L-amino acids FAT: MCT, soy, high oleic safflower or sunflower, M. alpina, and C. cohnii oils; corn oil (powder only) Vitamins, minerals 20 cal./fl. oz. Osmolality=	For infants with fat malabsorption, which may be associated with cystic fibrosis, short bowel syndrome, intractable diarrhea, or severe proteincalorie malnutrition, or intact protein sensitivity. Not recommended for use in very low birth weight infants. If Pregestimil is used as a milk substitute for children >12 months, total dietary	Non- breastfed infants Powder: 16 oz. RTF (2 oz.) Partially breastfed infants Powder: 16 oz. RTF (2 oz.)	7 cans 416 nursettes 1-3 months 3 cans 192	4-5 months 8 cans 448 nursettes 4-5 months 4 cans 224	6-11 months 6 cans 320 nursettes 6-11 months 3 cans 160
	of gluten	NDC: 0087-143341 24 cal/ounce: 2 oz. nursettes, 48 nursettes/case NDC: 0087-143441	$320 \text{ mOsm/kg H}_2\text{O} \text{ (powder)}$ $290 \text{ mOsm/kg H}_2\text{O} \text{ (} 20 \text{ cal/oz RTU)}$ $340 \text{ mOsm/kg H}_2\text{O} \text{ (} 24 \text{ cal/oz RTU)}$	calcium should be assessed for adequacy.		nursettes	nursettes	nursettes
Nutramigen® with Enflora LGG™ Toddler (Mead Johnson Nutrition)	Extensively hydrolyzed formula designed for older infants and children aged 9 – 36 months with cow's milk allergy	Powder: 12.6oz, 6 cans/case (use packed level scoops) Can yield = 86 fl. oz. (standard dilution) NDC: N/A	CHO: corn syrup solids, fructose, modified corn starch PRO: hydrolyzed casein, L-amino acids FAT: palm olein, soy, coconut, high oleic sunflower, M. alpina, and C. cohnii oils, Probiotic: Lactobacillus rhamnosus GG (powder only)	For older infants and children aged 9 – 36 months with cow's milk or soy formula allergy	Powder: 12.6 oz.	on-breastfed infi ially breastfed i Chil	8 cans	
	Lactose Free Galactose Free Contains no known sources of gluten		Vitamins, minerals Increased calcium and vitamins to meet needs of older infants and toddlers 20 cal./fl. oz. Osmolality= 300 mOsm/kg H ₂ O (pwd)					

Product Name	Description	Packaging	Composition	Indications	Maximum N	Monthly WIC Issuance Amounts
Pediasure Peptide 1.0 (Abbott Nutrition)	Nutritionally complete peptide-based formula for children. Gluten free Suitable for lactose intolerance Low residue Kosher Halal	Ready to feed: 8 oz bottles, 24 bottles/case (unflavored, vanilla, strawberry) NDC (for single bottle): Unflavored: 70074-0621-24 Vanilla: 70074-0621-20 Strawberry: 70074-0621-22	CHO: corn maltodextrin, short-chain fructooligosaccharides; sucrose (flavored only) PRO: whey protein hydolysate, hydrolyzed sodium caseinate FAT: interesterified canola oil, MCT Vitamins, minerals 30 cal/oz. Osmolality = 390 mOsm/kg H ₂ O (flavored) 250 mOsm/kg H ₂ O (unflavored)	For children 1-13 years of age with malabsorption, maldigestion or other GI conditions.	RTF 8 oz.	Children 113 bottles
Pediasure Peptide 1.5 (Abbott Nutrition)	Nutritionally complete peptide-based medical food. Gluten free Suitable for lactose intolerance Kosher Halal	Ready to feed: 8 oz bottles, 24 bottles/case (vanilla) NDC (for single bottle): 70074-0566-56	CHO: corn maltodextrin, short-chain fructooligosaccharides; PRO: whey protein hydolysate, hydrolyzed sodium caseinate FAT: interesterified canola oil, MCT Vitamins, minerals 44.5 cal/oz. Contains Nutraflora® scFOS® prebiotic Osmolality = 450 mOsm/kg H ₂ O	For children 1-13 years old with malabsorption, maldigestion or other GI conditions who are fluid restricted, have increased caloric requirements, or are at risk of malnutrition.	RTF 8 oz.	Children 113 bottles

Hypoallergenic Formulas—Elemental Formulas									
Product	Description	Packaging	Composition	Indications	Maximur	m Monthly W	IC Issuance /	Amounts	
Name	-								
PurAmino (Mead Johnson Nutrition™)	Nutritionally complete, hypoallergenic, amino acid–based formula for infants and toddlers with severe cow's milk protein allergy and/or multiple food protein allergies. Gluten Free Lactose Free Galactose Free Sucrose Free	Powder: 14.1 oz. can, 4 cans/case (use unpacked level scoops) Can yield = 98 fl. oz. (mixed to 20 cal/fl. oz.) NDC: 0087-510480	CHO: corn syrup solids, modified tapioca starch PRO: L-amino acids FAT: palm olein, coconut, soy, high oleic sunflower, M. alpina and C. cohnii oils Vitamins, minerals 20 cal. /fl. oz. Osmolality = 350 mOsm/kg H ₂ O	Infants and toddlers with cow's milk protein allergy and multiple food protein allergies, not effectively managed by an extensively hydrolyzed formula. When used as a milk substitute, the total calcium content of the diet should be assessed. Specialist intervention required.	Non-breastfed infants Powder: 14.1 oz. Partially breastfed infants Powder: 14.1oz.	8 cans 1-3 months 4 cans	4-5 months 9 cans 4-5 months 5 cans	6-11 months 7 cans 6-11 months 3 cans	
Elecare® (Abbott Nutrition)	A nutritionally complete amino acid based infant formula. 33% of fat from MCT Milk Protein Free Lactose Free Gluten Free Soy Protein Free Fructose Free Galactose Free Halal	Powder: 14.1 oz can; 6 cans/case (use unpacked level scoops) Can yield: 95 fl. oz. NDC: 70074-0535-11	CHO: corn syrup solids PRO: Free L-amino acids FAT: high oleic safflower, MCT and soy, M. alpina and C. cohnii oils Vitamins, minerals 20 cal/fl. oz. Osmolality = 350 mOsm/kg H ₂ O	For infants who cannot tolerate intact protein; designed for the management of protein maldigestion, malabsorption, severe food allergies, short-bowel syndrome, eosinophilic GI disorders, GI tract impairment and other conditions requiring an elemental diet. Specialist intervention required.	Non-breastfed infants Powder: 14.1 oz. 20 cal/oz Partially breastfed infants Powder: 14.1 oz. 20 cal/oz	9 cans 1-3 months 3 cans	4-5 months 10 cans 4-5 months 4 cans	6-11 months 7 cans 6-11 months 3 cans	

Hypoallergenic	Formulas—Elem	ental Formulas						
Product	Description	Packaging	Composition	Indications	Maximur	m Monthly W	IC Issuance /	Amounts
Name								
Elecare Jr. (Abbott Nutrition)	A nutritionally complete amino acid based medical food. 33% of fat from MCT Milk Protein Free Lactose Free Gluten Free Soy Protein Free Fructose Free Galactose Free Halal	Powder: 14.1 oz can; 6 cans/case (unflavored, vanilla) (use unpacked level scoops) Can yield: 62 fl. oz. NDC: Unflavored: 70074-0552-54 Vanilla: 70074-0565-86	CHO: corn syrup solids PRO: L-amino acids FAT: high oleic safflower, MCT and soy oils, DATEM Vitamins, minerals 30 cal/fl. oz Osmolality = 590 mOsm/kg H ₂ O	For children ≥12 months who cannot tolerate intact or hydrolyzed protein; designed for the management of protein maldigestion, malabsorption, severe food allergies, short- bowel syndrome, eosinophilic GI disorders, GI tract impairment and other conditions requiring an elemental diet. Specialist intervention	Powder 14.1 oz.	Chil	14 cans	
Neocate® Infant DHA/ARA (Nutricia North America)	Nutritionally complete, powdered amino acid based exempt infant formula containing nucleotides. 33% fat from MCT Lactose Free Sucrose Free Milk Free Halal	Powder: 14.1 oz. (400g) can, 4 cans/case (unflavored) (use unpacked scoops) Can yield = 97 fl. oz. (mixed to standard dilution of 20 cal/fl. oz) NDC: 49735-0125-95	CHO: corn syrup solids PRO: L- amino acids FAT: MCT, high oleic sunflower, sunflower, canola, M. alpina and C. cohnii oils Vitamins, minerals 20 cal./fl. oz Osmolality = 340 mOsm/kg H ₂ O	required. For infants with cow/soy milk protein allergy, multiple food protein intolerances, food allergy-associated conditions such as short bowel syndrome, eosinophilic esophagitis, malabsorption, gastroesophageal reflux or other GI disorders. Specialist intervention required.	Non-breastfed infants Powder: 14.1 oz. Partially breastfed infants Powder: 14 oz.	0-3 months 8 cans 1-3 months 4 cans	4-5 months 9 cans 4-5 months 5 cans	6-11 months 7 cans 6-11 months 3 cans

Hypoallergenic	Formulas—Elem	ental Formulas				
Product Name	Description	Packaging	Composition	Indications	Maximum M	onthly WIC Issuance Amounts
Neocate® Junior (Nutricia North America)	Nutritionally complete, powdered amino acid based medical food for children 35% of fat from MCT	Powder: 14.1 oz (400g) can, 4 cans/case (unflavored, tropical, chocolate) Can yield = 64 fl. oz. (unflavored), 60 oz. (flavored) NDC: Unflavored: 49735-0117-90 Tropical: 49735-0121-24 Chocolate: 49735-0126-90	CHO: corn syrup solids; sucrose (chocolate only) PRO: L-amino acids FAT: palm kernel, coconut, canola, high oleic safflower oils Vitamins, minerals 30 cal/fl oz Osmolality = 550 mOsm/kg H ₂ O (unflavored) 630 mOsm/kg H ₂ O (tropical fruit) 650 mOsm/kg H ₂ O (chocolate)	For children over 1 year of age with cow/soy milk allergy, multiple food protein intolerance, food allergy-associated conditions such as short bowel syndrome, eosinophilic esophagitis, malabsorption, gastroesophageal reflux or other GI disorders. Specialist intervention required.	Powder: 14 oz Unflavored Flavored	14 cans 15 cans
Neocate® Junior with Prebiotics (Nutricia North America)	Nutritionally complete, powdered amino acid based medical food with prebiotic fiber for children 35% of fat from MCT	Powder: 14.1 oz (400g) can, 4 cans/case (unflavored, tropical, chocolate) Can yield = 64 fl. oz. (unflavored), 61 (vanilla), 63 (strawberry) NDC: Unflavored: 49735-012912 Strawberry: 49735-016456 Vanilla: 49735-010627	CHO: corn syrup solids; fructooligosaccharide, inulin; sucrose (vanilla and strawberry only) PRO: L-amino acids FAT: palm kernel, coconut, canola, high oleic safflower oils Vitamins, minerals 30 cal/fl oz Osmolality = 550 mOsm/kg H ₂ O (unflavored); 630 mOsm/kg H ₂ O (strawberry); 650 mOsm/kg H ₂ O (vanilla)	For children over 1 year of age with cow/soy milk allergy, multiple food protein intolerance, food allergy-associated conditions such as short bowel syndrome, eosinophilic esophagitis, malabsorption, gastroesophageal reflux or other GI disorders. Specialist intervention required.	Powder: 14 oz	Children 14 cans

Product Name	Description	Packaging	Composition	Indications	Maximum I	Monthly WIC Issuance Amounts
Neocate Splash (Nutricia North America)	Hypoallergenic	Ready to feed: 8 fl. oz. drink boxes, 27 drink boxes/case NDC: Unflavored: 49735-0144-51	CHO: maltodextrin, sucrose PRO: L-amino acids FAT: refined vegetable oils (high oleic sunflower oil, MCT [modified palm kernel or coconut oil], canola oil Vitamins, minerals 30 kcal/fl oz Osmolality = 670 mOsm/kg H ₂ O (unflavored) 740 mOsm/kg H ₂ O (grape) 790 mOsm/kg H ₂ O (orange-pineapple)	For children 1 year of age or older with cow/soy milk protein allergy, multiple food protein intolerances, short bowel syndrome, eosinophilic esophagitis, malabsorption or other GI tract impairments. Specialist intervention required.	RTU 8 oz.	Children 113 boxes
Neocate's EO28 Splash (Nutricia North America)	acid-based liquid formula for children	Ready to feed: 8 fl oz drink boxes, 27 drink boxes/case NDC: Grape: 49735- 0126-70 Tropical Fruit: 49735-0126-66 Orange-Pineapple: 49735-0110-50	CHO: maltodextrin, sucrose (all); corn syrup solids (orange-pineapple) PRO: L-amino acids FAT: fractionated coconut, canola, high oleic sunflower oil, palm kernel Vitamins, minerals 30 kcal/fl oz Osmolality = 820 mOsm/kg H ₂ O	For children 1 year of age or older to supplement essential nutrients when child is on an elimination diet or has cow/soy milk protein allergy, multiple food protein intolerances, food allergy-associated conditions such as short bowel syndrome, eosinophilic esophagitis, or other GI tract impairments or malabsorption Specialist intervention required.	RTU 8 oz.	Children 113 boxes